

June 6, 2019

# Via Electronic Submission to PartDImprovements@mail.house.gov

The Honorable Richard Neal The Honorable Frank Pallone

Chairman Chairman

House Ways and Means Committee House Energy and Commerce Committee

The Honorable Kevin Brady The Honorable Greg Walden

Ranking Member Ranking Member

House Ways and Means Committee House Energy and Commerce Committee

# **Re: Part D Improvements**

Dear Chairman Neal, Chairman Pallone, Ranking Member Brady, and Ranking Member Walden:

The Center for Medicare Advocacy (Center) is pleased to provide the Committees feedback on their draft legislation and additional ways to improve the Part D program. The Center, founded in 1986, is a national, non-partisan education and advocacy organization that works to ensure fair access to Medicare and to quality healthcare. At the Center, we educate older people and people with disabilities to help secure fair access to necessary health care services. We draw upon our direct experience with thousands of individuals to educate policy makers about how their decisions affect the lives of real people. Additionally, we provide legal representation to ensure that people receive the health care benefits to which they are legally entitled, and to the quality health care they need.

#### Part D Out-of-Pocket Cap

The Center supports the establishment of a cap on out-of-pocket (OOP) Part D costs for all Medicare beneficiaries. This added protection from high prescription drug costs would be a significant improvement for beneficiaries, particularly those with chronic conditions, many of whom take multiple medications. While the low-income subsidy (LIS) program provides a backstop for those with very limited incomes, it does not reach many beneficiaries with very modest incomes. Therefore, without an out-of-pocket cap, such individuals are exposed to unbearable financial risk.

We urge Congress to consider a few factors when creating an OOP cap. For example, the draft legislation pegs the OOP cap to the current catastrophic threshold. If the cap is set at too high of

a threshold, fewer beneficiaries will hit the threshold and experience the relief from limiting their out of pocket expenses. We are also concerned that the draft fails to address the impending "cliff," when the catastrophic threshold will increase significantly. We strongly recommend that the draft legislation be amended to fix this cliff, indexing the threshold at the same rates as previous years.

As suggested by the National Council on Aging, we also encourage Congress to consider options for spreading out-of-pocket costs over the year so that beneficiaries do not incur unaffordable costs for the first few months before they reach the threshold. Congress should consider how to make a monthly or quarterly OOP cap work, rather than an annual cap.

Some proposals to restructure the Part D benefit suggest that, in addition to changing the reinsurance liabilities above the catastrophic threshold and establish an OOP cap, manufacturer coverage gap discounts should no longer count towards true out-of-pocket costs (TrOOP). The Center strongly opposes excluding manufacturer discounts from TrOOP costs. Even when combined with an OOP cap, the policy would increase OOP costs for many beneficiaries by keeping them in the coverage gap longer. Our hope is that Congress will pursue reforms that will make prescription drugs more affordable for Medicare beneficiaries, not less.

# Part D Low-Income Subsidy (LIS)

The Part D Low-Income Subsidy (LIS), or Extra Help, was designed to address the needs of low-income Medicare beneficiaries, but the program has significant flaws that should be addressed. Policymakers should consider reinvesting savings secured through restructuring of the Part D benefit to promote and expand access and affordability among the lowest income beneficiaries.

# Eliminate the Asset Test & Expand Eligibility

Many Medicare beneficiaries with limited incomes are not eligible or not enrolled in LIS because of the program's stringent eligibility thresholds that limit not only income, but also the assets a beneficiary can have. The asset test unfairly penalizes low-income beneficiaries for putting aside modest savings for retirement and emergency expenses, forcing them to spend down their assets.

Asset tests also discourage beneficiaries from attempting to enroll. Even those who would qualify find that collecting information on assets is a challenge and many give up simply because of the paperwork burden, which can be especially challenging for beneficiaries who are ill or have disabling conditions. As a result, many Part D enrollees with minimal income remain ineligible for this crucial cost-sharing assistance. Eliminating the asset test would also simplify the LIS application processing burdens for the Social Security Administration, and thus reduce administrative costs.

To ensure that all seniors with limited income have access to LIS, we recommend Congress eliminate the program's asset test and extend \$0 premiums, \$0 deductibles and fixed copays to Medicare beneficiaries under 200% FPL, as outlined in the Medicare Extra Rx HELP Act (S. 691) introduced by Sen. Casey. We also support Congress taking interim steps to raise the asset

limits and treat all retirement savings accounts the same as pensions, by counting the distributions as income but not counting the savings as assets.

Extend Automatic Enrollment in LIS to Individuals who Lose Medicaid Expansion Eligibility Turning 65

We support a recommendation by Justice in Aging to expand automatic enrollment in LIS to include individuals transitioning from expansion Medicaid to Medicare regardless of whether they are eligible for another category of Medicaid. Unfortunately, because of the difference in financial eligibility criteria, many seniors who are enrolled in expansion Medicaid lose their Medicaid eligibility when they turn 65 because their income and assets are too high to meet their state's aged/blind/disabled eligibility thresholds. While these individuals are most likely eligible for LIS, even under the current eligibility thresholds, they are not automatically enrolled because they are not eligible for Medicaid. Eliminating the necessity for these individuals to apply for LIS through the Social Security Administration would ensure that they get assistance with their Part D costs right away, and avoid unnecessary financial strain or delays in accessing prescription drugs.

Eliminate Cost-Sharing on Generics for LIS Beneficiaries

We recommend eliminating cost-sharing on generic drugs for LIS beneficiaries. Even a minimal amount of cost-sharing can be a barrier to access. While some plans do offer \$0 copay for some generics, applying a \$0 copay policy to all generics would both take the cost burdens off low-income beneficiaries and encourage both adherence and greater use of generics. It is important that reducing generic copays to \$0, however, not be accompanied by an increase in LIS cost-sharing for branded drugs.

#### Part D Exceptions and Appeals

The multi-level, protracted Part D exceptions and appeals process is onerous and time-consuming for Medicare beneficiaries, pharmacists, and prescribing physicians and often significantly delays access to necessary medications. Many Part D enrollees are unaware of both their right to appeal and how to go about initiating the appeals process<sup>1</sup>. Further, Part D enrollees are not provided individually-tailored information when refused a medication at the pharmacy counter, and such refusal does not trigger an appeal. This set up results in considerable time and effort on the part of the beneficiary and his/her physician trying to obtain enough information to affirmatively file an appeal, while many individuals who are denied at the pharmacy counter simply give up. We recommend the following improvements to the Part D exceptions and appeals process.

<sup>&</sup>lt;sup>1</sup>Presentation by Sokolovsky, L., Suzuki, S. and L. Metayer, "Part D exceptions and appeals" (September 2013), available at: <a href="http://www.medpac.gov/transcripts/part d exceptions & appeals.pdf">http://www.medpac.gov/transcripts/part d exceptions & appeals.pdf</a>; CMS, "Fact Sheets: Part D Reconsideration Appeals Data, Part D Fact Sheets CY 2011" (2011), available at:

### Individually-Tailored Notice at Pharmacy Counter

When a medication is denied, require that Part D plans provide beneficiaries with an individually-tailored notice that explains the reason behind the drug denial, as is required in the Medicaid program. We believe that access to information about the reason for a plan denial—provided at the pharmacy counter—will both eliminate significant beneficiary confusion and limit delays in accessing needed medications. Armed with information about why a prescription drug was refused at the pharmacy counter, Part D enrollees and their providers will be better equipped to determine the best course of action for the beneficiary's health.

# Denial at Pharmacy Should Trigger Appeal

Along these same lines, we strongly support allowing the pharmacy counter refusal to serve as the coverage determination by the Part D (or Medicare Advantage-Prescription Drug) plan. This proposal serves the dual purpose of removing a burdensome step for beneficiaries and their prescribers, first, by explicitly stating why the drug is not covered and, second, by expediting the appeals process for those who need it.

We note, with interest, a February 2014 letter<sup>2</sup> to then CMS Administrator Marilyn Tavenner, signed by every member of the Senate Finance Committee, stating in part: "We recommend improving the part D appeals process before any change to drug coverage. For instance, we encourage CMS to explore ways to allow the beneficiary to initiate the appeals process at the pharmacy counter when he/she is first notified the drug is not covered by the part D plan." It has been over five years since that bipartisan letter was sent. It is time for Congress to take action.

# Allow Tiering Exceptions for Specialty Tier Drugs

Tiering exceptions are currently not allowed for medications on the specialty tier—despite the fact these are among the highest cost medications, making them unaffordable for many beneficiaries with fixed incomes and limited resources. We strongly support the establishment of a cost-sharing exception and appeal process for drugs included on the specialty tier, both as a matter of fairness and to promote affordable access to high-cost medications.

### Use Part B Standards for Part D Off-Label Usage

In order to be covered under Part D, drugs must be prescribed for a "medically accepted indication," meaning their use for a particular disease must be approved by the FDA, or supported by one of three largely inaccessible Compendia, identified at Section 1927(g)(1)(B)(i) of the Social Security Act. (The Act was subsequently modified to allow coverage of anti-cancer

<sup>&</sup>lt;sup>2</sup> Senate Finance Committee letter is available at: <a href="https://califesciences.org/wp-content/uploads/2015/06/Senate-Finance-Committee-Bipartisan-Letter-Opposing-Elimination-of-Six-Protected-Classes-of-Prescription-Drugs-from-Medicare-Part-D-February-5-2014.pdf">https://califesciences.org/wp-content/uploads/2015/06/Senate-Finance-Committee-Bipartisan-Letter-Opposing-Elimination-of-Six-Protected-Classes-of-Prescription-Drugs-from-Medicare-Part-D-February-5-2014.pdf</a>.

drugs if their use is supported in peer review journals.) Under Part B, however, all drugs, not just those used in an anti-cancer regimen, may be supported by peer reviewed literature.<sup>3</sup>

This inconsistency with standard practice of many other insurers (including private insurance and state Medicaid programs) has created serious barriers to access to effective and sometimes life-saving prescription drugs and has been a source of frustration to providers and beneficiaries alike. We recommend that Congress align the Part D program with current standards of "medically accepted indication" currently applicable to Part B.

# Conclusion

We appreciate the opportunity to submit these comments. For additional information, please contact David Lipschutz, Senior Policy Attorney, <u>dlipschutz@medicareadvocacy.org</u>, at 202-293-5760.

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<sup>&</sup>lt;sup>3</sup> See "CMA Report: Medicare Coverage for Off-Label Drug Use" (September 2010), available at: <a href="https://www.medicareadvocacy.org/cma-report-medicare-coverage-for-off-label-drug-use/">https://www.medicareadvocacy.org/cma-report-medicare-coverage-for-off-label-drug-use/</a>; also see CMA Weekly Alert "Medicare Part D and Off-Label Rx Denials" (June 2016), available at: <a href="https://www.medicareadvocacy.org/medicare-part-d-and-off-label-rx-denials/">https://www.medicareadvocacy.org/medicare-part-d-and-off-label-rx-denials/</a>.